

findtheDOT

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**Presentation by
Stuart Creque,
Vice President, Business Development,
findtheDOT, Inc.**

**before the
U.S. Food and Drug Administration**

**Public Meeting on
Bar Code Label Requirements for Human Drug Products
[Docket No. 02N-204]
July 26, 2002**

Thank you for allowing me to make this presentation to you today regarding the Food and Drug Administration's planned regulation on machine-readable labeling for human drug products. FindtheDOT has developed a unique new technology for creating links between physical objects and digital data that relates to those objects. This alternative to bar code solves the problems that have so far prevented wider acceptance of machine-readable codes for patient safety.

Automated identification of unit of use packages at the patient bedside is a key element – and the last line of defense – in preventing medication errors in the clinical setting. While bedside verification systems using traditional bar codes have shown good success (when used as designed) in reducing medication administration errors, these systems have not achieved widespread acceptance. This is due to three factors:

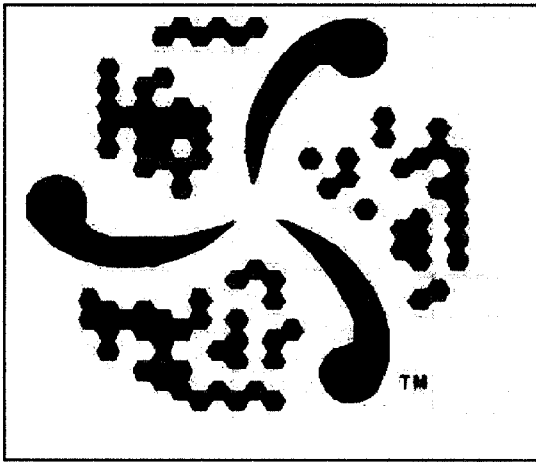
- ❖ Cost of packaging unit of use medications to fit bar codes. Bar codes are big and thus require big packages, which waste material and add cost.
- ❖ Cost of the bedside verification system. Bar code scanners are relatively expensive, and are incorporated into very costly systems requiring major IT investments. If the current bar codes are replaced by an RSS or conventional matrix code, the acquisition cost of scanning hardware will rise substantially.
- ❖ Reluctance of bedside staff to utilize unwieldy bar code scanning hardware and software. Bar code scanners are inconvenient at the bedside and the software driving them is generally complex, slowing down the bedside nurse.

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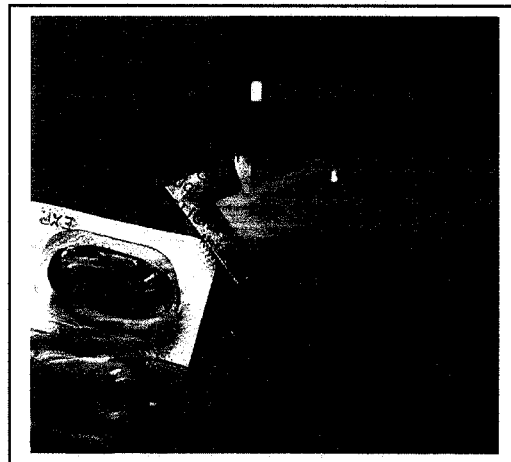
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FindtheDOT's Med Dot technology improves both sides of this trade-off by offering:

- ❖ A code physically small enough – just 5mm in diameter – to fit onto existing packaging;
- ❖ Low-cost code readers within the reach of hospital capital budgets; and
- ❖ A linking mechanism whereby any Med Dot can link to a related data set that can contain any types and quantity of data, both static and dynamic.



Med Dot, greatly enlarged



Med Dot reader in operation

This removes the barriers both to rapid deployment of machine-readable codes on unit of use packages and to rapid implementation of bedside scanning systems at hospitals. Further, because Med Dots support a code space of 10 billion billion unique values, each and every unit of use medication, biologic product and medical device can have a unique identifier linked to its specific design, manufacturing and use data.

A manufacturer can pre-print Med Dots onto packaging material, inspect them off-line, and pre-load the database with product information. At the time of packaging, the manufacturer updates the Med Dot database with the lot number and expiration date. When the product is sold, the data can be transferred to a local system at the purchasing hospital.

On the nursing floor, a nurse uses a Med Dot reader to identify the patients assigned to her that shift. Each of her patient's medication orders are wirelessly transmitted to her Med Dot reader. As she prepares to administer a medication, she reads Med Dots on the patient wristband and the unit of use package and receives positive confirmation if the Five Rights of medication safety are satisfied. The device can prompt for further data, such as route of administration, and can accept charting notes from a pocket menu card.

The system thus supports automated charting as well as reporting of “near misses” or averted errors.

This simple technology can be incorporated easily with existing hospital IT systems. Moreover, findtheDOT will gladly license the Med Dot reading capability to vendors of bar code based systems. We will also license pharmaceutical manufacturers and bar code equipment manufacturers at very low cost in order to make Med Dots a healthcare standard.

The Med Dot is an innovative technology that breaks the existing logjam in acceptance of machine-readable codes for bedside verification. As such, it offers an immediate increase in patient safety. Thank you.



**Statement of
findtheDOT, Inc.**

**before the
U.S. Food and Drug Administration**

**Public Meeting on
Bar Code Label Requirements for Human Drug Products
[Docket No. 02N-204]
July 26, 2002**

BACKGROUND

FindtheDOT, Inc., is a privately-held developer of an innovative technology for linking physical objects to digital data using a printed, machine-readable code. We are grateful for the opportunity to offer these comments to help the Food and Drug Administration formulate its planned regulation on bar code labeling for human drug products.

FindtheDOT has developed a unique new technology for creating links between physical objects and digital data that relates to those objects. This technology consists of a printed code symbol, a low-cost reading methodology, and an indirect look-up method that maximizes both the use of the symbol's code space and the flexibility of data types and scope that can be linked. These characteristics make the new technology, which we call "Med Dots," an ideal solution to the problems that have impeded adoption of bar codes for medication error reduction to date.

ISSUE

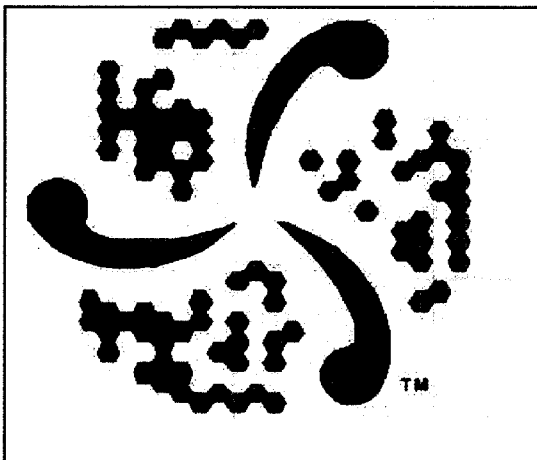
Automated identification of unit of use packages at the patient bedside is a key element – and the last line of defense – in preventing medication errors in the clinical setting. While bedside verification systems using traditional bar codes have shown good success (when used as designed) in reducing medication administration errors, these systems have not achieved widespread acceptance. This is due to three factors:

- 1) Cost of packaging unit of use medications to fit bar codes, leading to reduced availability

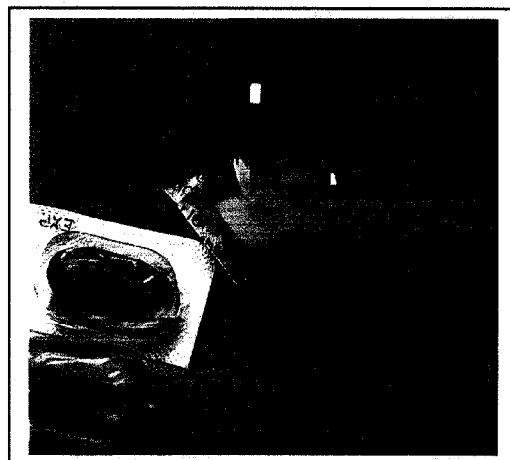
- 2) Cost of the bedside verification system
- 3) Reluctance of bedside staff to utilize unwieldy bar code scanning hardware and software

Traditional 1-D bar codes require substantial package surface area, requiring packaging that is larger than otherwise needed for a unit of use. This excess cost deters manufacturers from placing bar codes on their products because they add cost without offering value to the vast majority of their customers. Moreover, the current bar code schemas in use do not include desirable data such as lot number: adding this data to the code exacerbates the package size/cost problem. Attacking this problem by substituting an RSS or conventional matrix code substantially increases the acquisition cost of the scanning hardware, making adoption by hospitals less likely.

FindtheDOT's Med Dot technology improves both sides of this trade-off by offering a code physically small enough (5mm diameter) to fit onto existing packaging, low-cost code readers within the reach of hospital capital budgets, and a linking mechanism whereby any Med Dot can link to a related data set that can contain any types and quantity of data and that can be dynamically updated. This innovation removes the impediments both to rapid deployment of machine-readable codes on unit of use packages and to rapid implementation of bedside scanning systems at hospitals.



Med Dot, greatly enlarged



Med Dot reader in operation

RECOMMENDATIONS

FindtheDOT offers the following recommendations in response to the FDA's questions. FindtheDOT's recommendations are made in the context of a physically small printed code symbol with a vast code space, low-cost reading devices, and the ability to link any type and quantity of data to any given code value.

A. Machine-Readable Labeling of Drugs and Biologics

1. **Products to be coded:** At a minimum, machine-readable codes should be required for unit of use drug and biologic packages used in the institutional environment, including both prescription and over-the-counter medications. FindtheDOT's Med Dots have an available code space of over 10 billion billion values, enough to assign a unique identifier to each and every unit of use package produced in the world. Med Dots are suitable for use in non-institutional settings as well, and the cost to add them to those products is minimal. Applications for home monitoring of medication safety would evolve from having Med Dots on consumer packaging.
2. **Data elements to be included in code:** Because it is a linking code, the Med Dot code allows direct access to compound information, including contraindications and interactions, and lot number and expiration date. The code does not have to contain this information itself: instead, it links to a set of databases containing the information. These databases include the static data (compound ID, lot number, expiration date) and the dynamic data (who/when administered, under which medication order, etc.) for each individual dose. Compound data permits bedside alerts to specific precautions or interactions, and lot number and expiration date is a useful safety precaution to prevent administration of contaminated or expired products. The Med Dot linking architecture makes it unnecessary to "skimp" on data elements to save code space.
3. **Code symbology:** In the near term, the FDA should not require or prohibit the application of bar codes beyond the widely used linear, one dimensional bar code symbology that conforms to HIBCC or UCC/EAN standards. Hospitals with existing systems set up to use bar codes will want to have continued access to bar coded products. However, the FDA should allow manufacturers to utilize such symbologies as the Med Dot in parallel with the traditional bar code on existing bar coded products, and in lieu of bar codes on products where the unit of use packages are currently too small to support traditional bar codes. Forcing traditional bar codes onto the 70 percent of products that do not currently use them would be an excessive burden on manufacturers, requiring them to retool their production lines and incur higher materials costs to benefit only a fraction of hospitals and patients. On the other hand, requiring Med Dots on those unit of use packages too small to accommodate bar codes will give hospitals confidence that they will have machine-readable product to use with newly-acquired bedside verification systems. As an aside, it is findtheDOT's intention to license the Med Dot technology widely and at minimal cost to drug and biologics manufacturers as well as to manufacturers of bar code readers and other hardware devices.

4. **Code location & containers to be bar coded:** The Med Dot is small (5mm diameter), readable from any angle, and distinctive in appearance. Manufacturers should have the flexibility to fit it into any available spaces on existing labels.

For safety, the code should be applied to unit of use container to be opened at the bedside to reduce the possibility of confusion between the time the code is read and the time the product is administered. Unit of use containers come in various shapes and sizes – oral solids, oral liquids, topical creams, pre-packaged unit-dose syringes, vials, and ampules – and some are unsuited to bar codes. Med Dots are much easier to print than bar codes and much easier to fit onto small or irregular packages.

5. **Products already coded:** No products are currently coded with Med Dots. However, less than 30 percent of drugs are now bar coded at the unit of use level, whereas over 95 percent are bar coded at the outer carton level as a result of purchaser demand for inventory control and other reasons. Bar codes are well-suited to inventory control and other commercial and industrial functions, but are ill-suited to the specific needs of bedside verification and patient safety.

B. Machine-Readable Labeling of Medical Devices

1. **Medical device codes:** As a linking code, the Med Dot allows any relevant data (from manufacturing lot to design and testing data) to be linked to the device. The Med Dot itself becomes a unique identifier for the medical device, enabling tracking of data at the unit level.
2. **Products to be coded:** FindtheDOT recommends that all medical devices carry a machine-readable code. As a linking code, the Med Dot allows any relevant data (from manufacturing lot to design and testing data) to be linked to the device. The code space (10 billion billion combinations) allows for unique identification of each and every device, down to each tongue depressor. Its small size allows the Med Dot to fit onto all types of device.
3. **Coding of reprocessed product:** FindtheDOT recommends that all reprocessed, repackaged, refurbished or multiple-use medical devices carry a machine-readable code. For products with a permanently embossed code (e.g., surgical steel object) or for multi-use products, the original manufacturing and use data can be archived and the code linked to a new data record each time the product is re-used. For products where the code label can be replaced, the old data can be archived and a new Med Dot code can be assigned to the product.
4. **Benefits of coding devices:** A Med Dot code on each device permits a uniform means of accessing device information. Reading the Med Dot automatically

retrieves the data associated to that device without the user's having to contact the device manufacturer. The data can be contextualized (i.e., reading the Med Dot in one context can call up the device usage history, while reading it in another can call up the device's design data). Also, having a Med Dot code preassigned to each device supports tracking within the hospital; for example, Med Dots on specimen containers would minimize the incidence of specimens confused or lost on the way to the lab.

C. General Issues and Economic Impact of Machine-Readable Labeling

1. **Printing costs:** The Med Dot technology minimizes these costs as compared to other symbologies. Only 5 mm across and readable from any orientation, Med Dots fit onto existing packaging, avoiding the cost of re-tooling. Med Dots can be printed before packaging occurs, validated by 100 percent inspection before the packaging line. When the Med Dots are used in packaging, the data linked to each Dot is updated to reflect the manufacturing lot and date, and the codes themselves need only be spot-checked for final validation.
2. **Implementation:** FindtheDOT is the inventor and licensor of the Med Dot. It is a 5 mm diameter round symbol, readable from any orientation, and has a code space of over 10 billion billion unique values. Used as a linking code, it allows any item to be linked to a unique data set with any number of static (e.g., compound, lot number, etc.) and dynamic (e.g., dispensing and administration history, etc.) elements. It is findtheDOT's intention to license the Med Dot technology widely and at low cost to support rapid adoption into patient safety applications.
3. **Verification:** Med Dots can be printed before packaging occurs, validated by 100 percent inspection before the packaging line. When the Med Dots are used in packaging, the data linked to each Dot is updated to reflect the manufacturing lot and date, and the codes themselves need only be spot-checked for final validation. This minimizes the need for high-speed, real-time code reading systems in the production environment.
4. **Unique codes at production speeds:** By printing Med Dots before packaging occurs, the need to print at high-speeds in real time is avoided. The code space available with Med Dots (10 billion billion unique values) means that every single unit of use package can have a completely unique identifier and linked data set for tracking and reporting, from manufacturing through to administration.
5. **Equipment:** FindtheDOT offers software engines for generating Med Dot codes in mass volumes, a lookup system and architecture for maintaining the linkage from each unique Med Dot to its related data set, and vision systems required for production verification. FindtheDOT also offers the devices used for bedside

verification of medications. FindtheDOT intends to license these technologies to pharmaceutical and device manufacturers, bar code reader manufacturers and other parties at a very low cost in order to help make Med Dots a standard symbology for patient safety applications.

6. **Technology acceptance:** In the 12 years since the formation of the Healthcare Industry Business Communications Council, less than 5 percent of hospitals in the U.S. have adopted bar codes for patient safety, despite the urgency of the medication error problem and the many pressures on hospitals and other industry participants to solve the problem. This is because bar codes are a technology ill-suited to the specific needs of healthcare in the clinical environment. Bar codes are too unwieldy and bar code reading systems too costly for widespread industry acceptance.

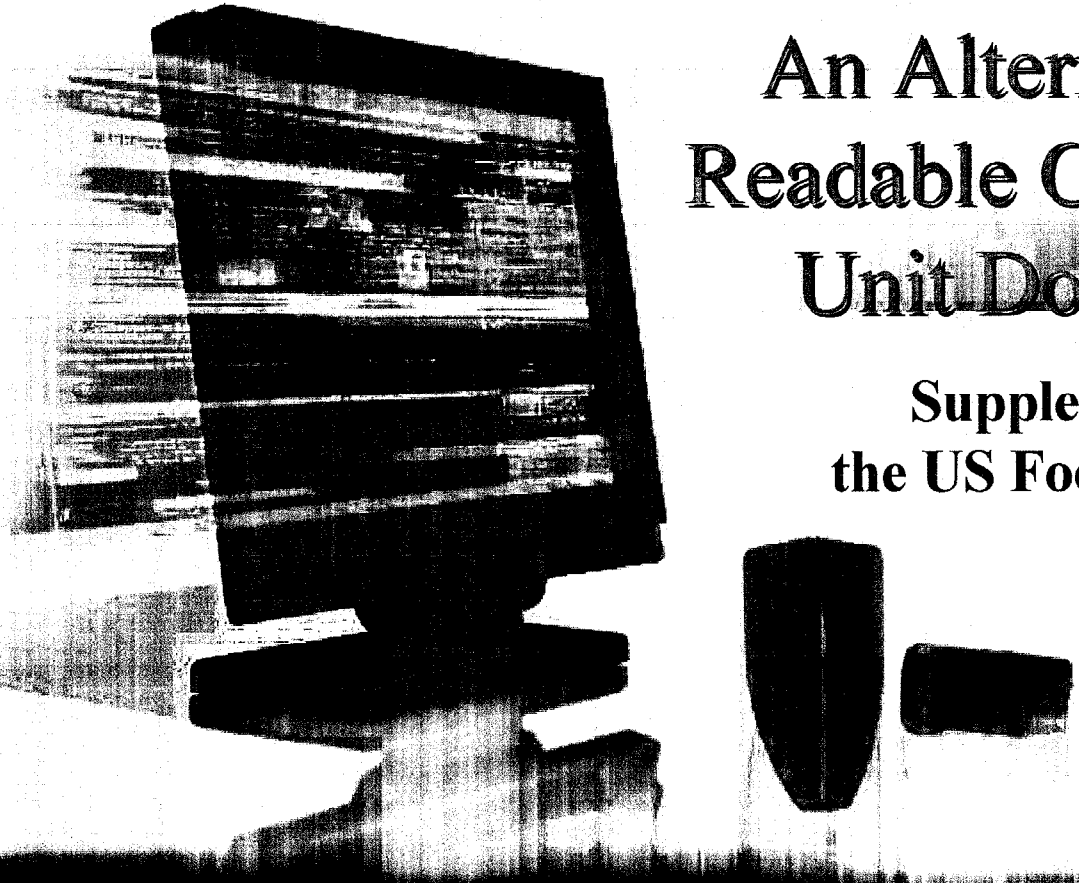
The experience of other industries shows that a code reading technology that offers a practical, affordable and effective solution to a commercial problem will find near-universal acceptance. FindtheDOT offers such a technology for healthcare. Med Dots are practical and affordable for incorporation onto unit of use packaging, and Med Dot readers are affordable for hospitals and practical for bedside verification. Taken as a system, this technology offers an effective solution for patient safety, one that is flexible enough to support automated note-taking for charting, reporting of avoided errors, inventory control of consumables, lab specimen tracking, order entry, and other healthcare applications.

7. **Phase-in schedule:** The FDA should allow sufficient lead time for manufacturers to re-tool packaging operations, purchase new printing and verification equipment, redesign package artwork, and file for label re-approvals. The Med Dot technology minimizes this lead time as compared to other symbologies.

Machine-readable codes on drug labels will increase patient safety if and only if hospitals implement equipment and systems to use the codes for safety purposes. It is imperative to create regulations that allow and assist hospitals in acquiring and implementing bedside verification systems that are affordable, practical and effective.

CONCLUSION

The Med Dot is an innovative technology that breaks the existing logjam in acceptance of machine-readable codes for bedside verification. As such, it offers an immediate increase in patient safety in the U.S., because the faster the adoption of machine-readable codes by manufacturers and hospitals, the faster the processes will be put in place to prevent medication errors. FindtheDOT is ready to provide the support needed to make Med Dots a standard in healthcare.



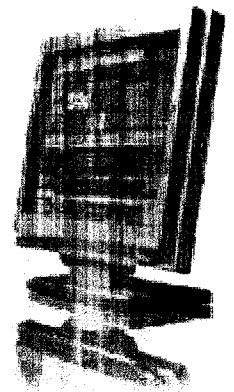
findtheDOTTM

An Alternative Machine-
Readable Coding Scheme for
Unit Dose Medications

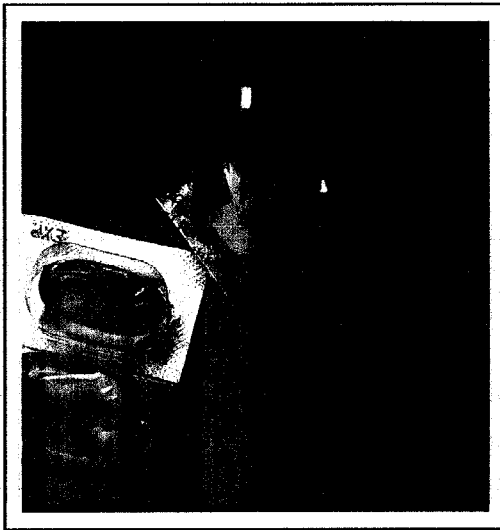
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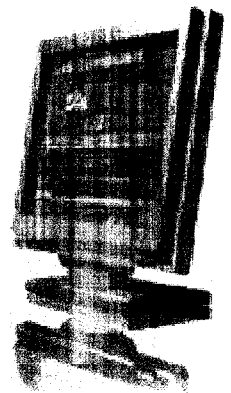
- ***Patient Safety Depends on Verifying the “Five Rights” of Medication Administration***
- ***Quality Depends on Measurable Systems***
- ***Bar Codes and the Bad Trade-off***
- ***Bar Code Legacy Systems: What Do They Have in Common?***
- ***The Answer: a Linking Code***
- ***Comparing Med Dots to Bar Codes***
- ***The Med Dot Patient Safety Solution***
- ***Solution Architecture & Its Advantages***
- ***Cost Advantages***
- ***Licensing Med Dots Industrywide***



The Rights of Medication Administration

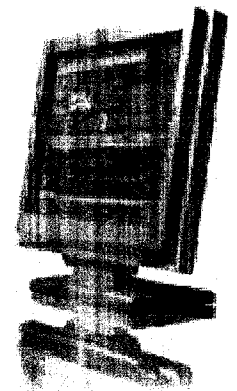


- Right patient
- Right medication
- Right dose
- Right time
- Right route – delivery method (oral, injected, etc.) and site (right or left eye, etc.)



Quality Depends on Measurable Systems

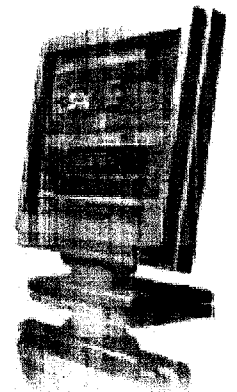
- The value of the system lies in verifying 100 percent of medication administration actions and recording (measuring) every one of those actions
 - Measurement is critical to subsequent root-cause analysis and other systemic approaches to error prevention
 - The measurement gives a denominator to calculate true error rates
- Every patient caregiver (RN, LVN/LPN, etc.) must have a validation and measurement tool



Code Based Approaches

Data about medication is embedded in the code

- Implies generating & printing codes on the fly
- New data requirements = new codes on packages
- More data = bigger code
- Still requires lookup from database to compare content of code to medication order



Trade-off of Bar Codes

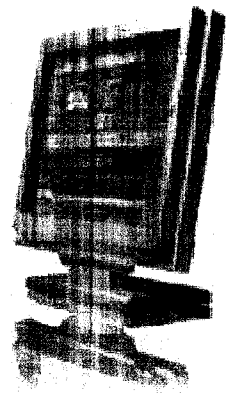
Symbol size vs. cost of equipment

- 1-D (traditional) bar codes require large packaging area
 - Increases costs of packaging, storage, transportation
 - Require laser scanners for maximum reliability and convenience
- RSS or 2-D (matrix) codes require less packaging area
 - Decreases packaging & related costs
 - Substantially increases system implementation costs due to more sophisticated, expensive readers



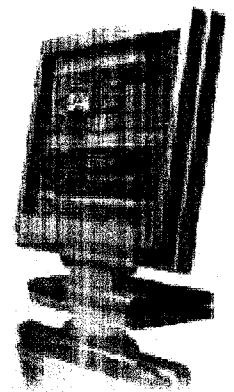
Answer with Bar Codes

- *With traditional bar codes, packaging costs (including retooling production lines) dissuade manufacturers and hospitals have difficulty justifying moderately expensive bar code readers*
- *If the manufacturer tries to reduce packaging costs using RSS or matrix codes, the hospital is even less able to afford to implement the system due to the prohibitive cost of the code readers*



Code Legacy Vendors

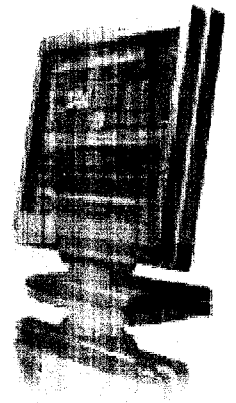
- Baxter (Deerfield, IL) – Autros™
- Becton, Dickinson (Franklin Lakes, NJ) – BD.id-Rx™
- Bridge Medical (Solana Beach, CA) – MedPoint™
- Cardinal Health (Dublin, OH) – Pyxis division – VeriFive™
- McKesson (San Francisco, CA) – Horizon Admin-Rx™
- Siemens Health Services (Malvern, PA) – Med Administration Check



Do They Have in Common?

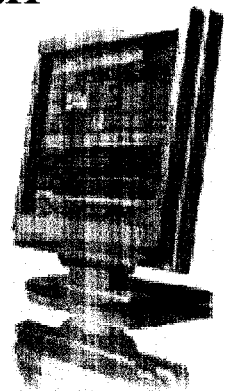
- All offer similar solutions
- All use 20-year old industrial bar-code technology
- Total market share is 3%

The shortcomings of bar codes compromise patient safety: 97% of US hospital patients don't have protection against bedside medication errors



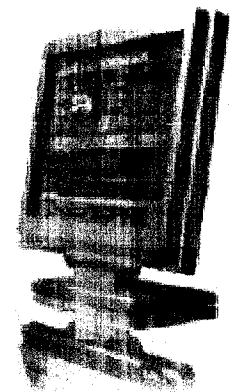
A new code symbol and reader with these ideal characteristics:

- A “linking code” that links the medication to a database entry that can be dynamically updated
- Large code space: every dose of every medication gets a unique serial number (critical in the era of genomics)
- Small size: fits onto economically-sized unit dose packages with little, if any, redesign
- Low-cost reader: equipping every patient caregiver with a code reader is affordable
- Ease of operation: doesn't require careful alignment, extensive software training



Uses of a Linking Code

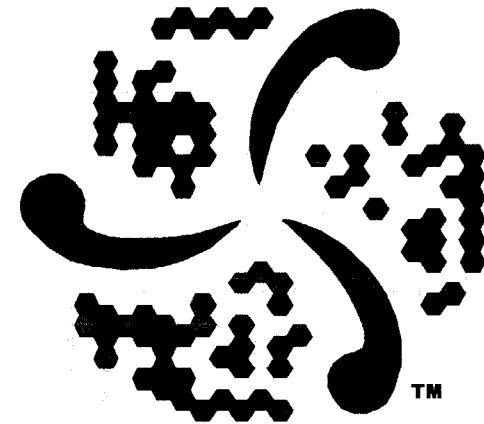
- Static information (e.g., manufacturer, NDC number, lot, expiration date, etc.) can be added to database at any time
 - *Codes can be pre-printed on packaging material, then associated to specific product/plant/line/lot/date information after packaging run*
- Dynamic information (e.g., sales history, medication order details, dispensing history, administration details, genomic customization, lot recalls, etc.) can be tracked for each individual dose
- Same code symbol can be used to identify patient, caregiver, port on IV or other line, etc.
- Same code symbol on paperwork and accessory cards permits automatic charting, documentation, charge capture, etc.



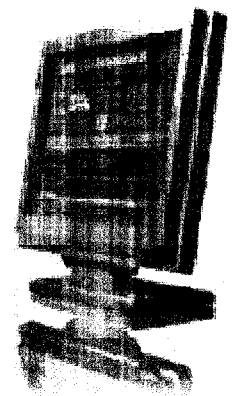
Med Dots v. Bar Codes

Bar codes are missing these five critical features:

- **Small** — 5 mm diameter
- **Reliable** — Forward Error Correction; round shape can be read at any angle
- **Low Cost Reader** — a personal reader can sell for under \$100.
- **Encrypted** — unique and encrypted
- **Huge Code Space** — 500 unique Med Dots for every human being on Earth, every day, for 1,000 years

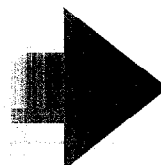


Enlarged
Med Dot



Comparison

Existing Approaches



Med Dot Solution

Cost

Bar code readers cost \$300 to \$1150 each.

Wireless Med Dot readers cost \$100.

Ease of Deployment

Other systems require expensive and potentially interfering 802.11 hospital-wide wireless network. Extensive training required.

No new network required. The wireless link is direct to the nurse's station PC—30 foot range, in 900 MHz ISM band. Minimal training required.

Compatibility

1-D bar codes are 20X times larger and require secondary drug packaging to hold the large bar code label.

Small (5 mm), round Med Dot fits on unit-dose packaging.

Ease of Use

Industrial bar code scanners weight 8 oz to 2.5 lbs. Often must be attached fragile PDA. Multiple steps are required to scan a bar code.

Dedicated wireless Med Dot reader weighs 1.25 oz. Shirt-pocket friendly. No keyboard. No docking. Automatic data synchronization and recording.

Safety All Five Rights

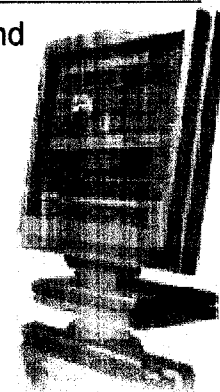
Existing systems often miss key rights (such as omission, abuse, or wrong time) because bar codes are not unique nor specific to patient.

Each Med Dot is unique to a single-dose for a single patient. Prevents abuse, and tracks errors to the cause of the error.

Expandability

Bar code systems are force-fit into other applications within the hospital.

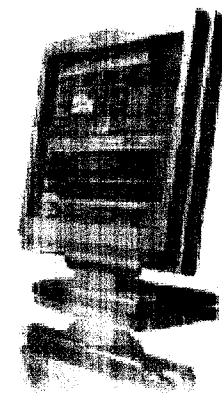
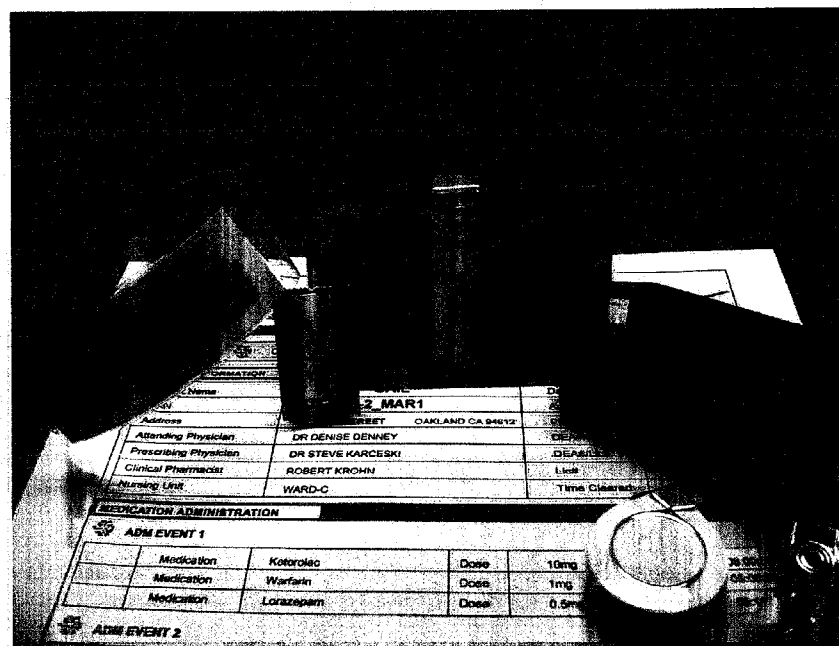
Med Dots naturally fit into billing, ordering, and other hospital applications.



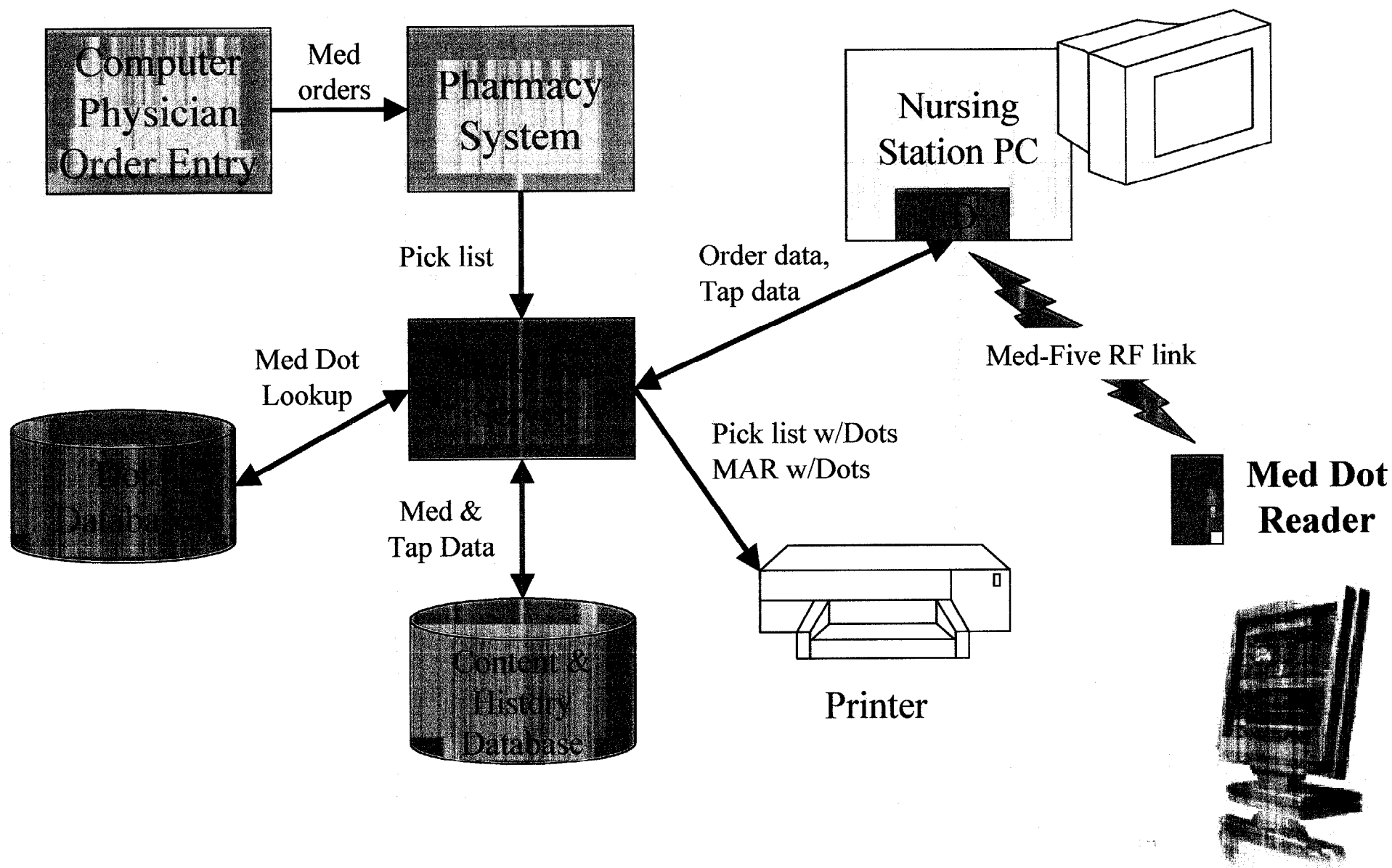
Patient Safety Solution

Med Dots in a Patient Medication Safety System

- Medications are prepared in the hospital pharmacy in unit doses.
- Each dose is marked with a “Med Dot” (unique machine-readable code)
- The nurse taps the Med Dots with her “Dot Finder” (compact wireless reader)
- The electronic Dot Finder provides instant validation of all five rights.
- The system automatically records details of medication given (patient, nurse, time, drug, dose, route, notes)

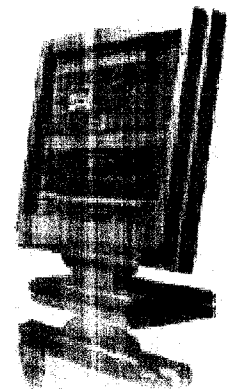


Architecture



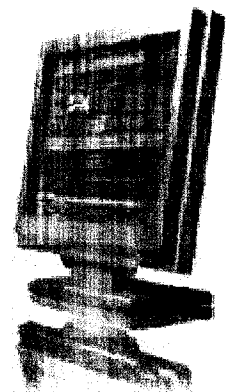
Key Advantages

- Med Dots can be “layered” on top of existing pharmacy information systems without extensive reprogramming
 - The Med Dot layer “listens” to medication orders after they are verified by the pharmacy system, as they are transmitted to the nursing unit
 - The Med Dot identification and validation layer adds richness and specificity to medication orders
- Med Dots can be incorporated easily into existing bedside verification solutions



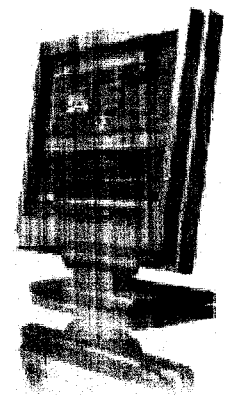
Printing Cost Advantages

- Med Dots can be printed on existing packaging with little marginal cost
 - No expensive retooling of packaging lines for “on the fly” coding
 - No packaging material added just to print codes
 - Potential savings of hundreds of \$millions annually
- Affordability and ease of implementation mean greater uptake by manufacturers and more universal availability to hospitals



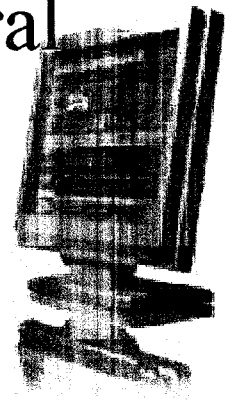
Cost Advantages

- Med Dot technology is much more affordable for the hospital
 - Equipping 2.4 million RNs, LVN/LPNs, CNAs with Med Dot readers saves between \$500 million and \$2.5 billion compared to bar code scanners
 - Equipping 5,800 hospitals saves several \$billion more in reduced system implementation costs
- Affordability means more universal utilization and better, more widespread protection of patients



Medication Industrywide

- findtheDOT will license Med Dot printing technology at minimal cost (i.e., no per-package royalties) to every pharmaceutical & biologic product manufacturer and packager
- findtheDOT will license any interested manufacturer to produce Med Dot readers
- findtheDOT will license any interested systems integrator to utilize Med Dots for patient safety
- Licensing fees will be used to maintain a central registry of Med Dot codes for the industry



a Real Difference

“findtheDOT’s technology has the potential to dramatically reduce medical errors and thereby increase the quality of patient care.”

—Dr. David B Nash, MD, MBA
Dean and Director, Jefferson Medical College
Advisor to findtheDOT

Med Dots will save hundreds of lives and billions of healthcare dollars each year.

